



Memorandum

Date JUL 17 1998
From June Gibbs Brown
Inspector General *June G Brown*
Subject Review of the Food and Drug Administration's Citizen Petition Process
(CIN: A-15-97-50002)
To Michael A. Friedman, M.D.
Lead Deputy Commissioner
Food and Drug Administration

The attached final report provides you with the results of our review of the Food and Drug Administration's (FDA) citizen petition process. We reviewed FDA's effectiveness in handling citizen petitions and identified ways that the process can be improved.

If you have any questions, please call me or have your staff contact Joseph J. Green, Assistant Inspector General for Public Health Service Audits, at (301) 443-3582. To facilitate identification, please refer to Common Identification Number A-15-97-50002.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF THE FOOD AND DRUG
ADMINISTRATION'S CITIZEN
PETITION PROCESS**



**JUNE GIBBS BROWN
Inspector General**

**JULY 1998
A-15-97-50002**

EXECUTIVE SUMMARY

BACKGROUND

This final report provides the results of our review of the Food and Drug Administration's (FDA) effectiveness in handling citizen petitions. The FDA regulations¹ permit any person to submit a citizen petition to FDA requesting the Commissioner of Food and Drugs to: (1) issue, amend, or revoke a regulation or order; or (2) take or refrain from taking any other form of administrative action.

OBJECTIVE

The objective of this review was to assess FDA's effectiveness in handling citizen petitions and identify ways that the process can be improved.

SUMMARY OF FINDINGS

The FDA does not have an effective process for handling citizen petitions in a timely manner, as evidenced by a backlog of approximately 250 petitions that have not been fully answered, some dating to the 1970's and early 1980's. The FDA regulations require tentative or final responses to citizen petitions within 180 days. The backlog of pending petitions includes issues that the petitioners believe are matters of public safety, and some have requested FDA to ban or withdraw approval of certain products. When FDA does not answer petitions in a timely manner, the public may lose confidence in the regulatory process. Because the citizen petition process is not a high priority among FDA's various responsibilities, the agency has provided limited resources to the process, and there is little central oversight of the process across FDA program areas. Recognizing its problems with the petition process, FDA developed options during the early 1990's to improve the process; and since the start of our review, closed out slightly more petitions than it has received. We believe, however, that more can be done to reduce the backlog.

RECOMMENDATIONS

We recommend that the Commissioner of Food and Drugs:

1. Correspond with petitioners whose requests are of long standing to determine if they still want FDA to take action on their petitions;

¹ Code of Federal Regulations (C.F.R.) Title 21, Part 10, Subpart B, Section 10.30.

2. Publish a notice in the Federal Register for petitioners who do not respond to FDA's correspondence, notifying them that their petitions will be removed from agency records and the reasons why unless advised otherwise;
3. Establish time-phased target dates for eliminating the remaining citizen petition backlog by handling first the oldest petitions with the most serious public health implications;
4. Include in all tentative responses to petitioners an estimate of when a final response will be issued and, to the extent possible, a preliminary indication of whether FDA will approve or deny the petition;
5. Develop agency-wide optimal policies and procedures to be used by all organizational components for responding to citizen petitions;
6. Include time spent working on citizen petitions as a category of the agency's time reporting system; and
7. Establish management and oversight responsibility for the citizen petition process in the Office of the Commissioner (OC) and implement a reporting system in which all citizen petitions still pending after 1 year are reported to o c .

On June 18, 1998, we received FDA's written comments to the recommendations contained in a draft of this report, issued on March 25, 1998. The FDA provided general and technical comments, which we incorporated where appropriate. In terms of our recommendations, the agency basically agreed with numbers 1, 2, 3, 5, and 6. The FDA did not concur with recommendation number 4 regarding the agency being more informative in its tentative responses. In addition, FDA stated it was unclear on the need for recommendation number 7, which called for OC management and oversight of petitions pending after 1 year. We discuss FDA's comments and our views in the section entitled, "FDA Comments and OIG Response." The FDA comments are included in their entirety in Appendix B.

TABLE OF CONTENTS

	<u>Page</u>
EXECUTIVE SUMMARY	i
INTRODUCTION	1
BACKGROUND	1
OBJECTIVE, SCOPE, AND METHODOLOGY	1
RESULTS OF REVIEW	3
FDA IS REQUIRED BY REGULATION TO RESPOND TO CITIZEN PETITIONS	3
CITIZEN PETITIONS ARE NOT ANSWERED IN A TIMELY MANNER	3
HEALTH AND SAFETY ISSUES NOT BEING ADDRESSED	4
INEFFECTIVE CITIZEN PETITION PROCESS CAUSED BY SEVERAL FACTORS	5
Limited Resources	5
Policies and Procedures	6
Screening and Prioritizing System	6
Tentative Responses	6
Management and Oversight	7
FDA Has Studied the Citizen Petition Process, But Has Not Implemented Most Recommendations	7
CONCLUSIONS	8
RECOMMENDATIONS	8
FDA COMMENTS AND OIG RESPONSE	9
APPENDIX A	
APPENDIX B	

INTRODUCTION

BACKGROUND

The FDA is the Federal agency responsible for regulating foods, drugs, biologics, cosmetics, radiation-emitting electronic products, and medical devices--commodities that affect the daily lives of all Americans. The FDA provides the public with various opportunities to influence the way it regulates these products. One way is through the citizen petition process.

The FDA regulations permit any person to submit a citizen petition to the agency requesting the Commissioner of Food and Drugs to: (1) issue, amend, or revoke a regulation or order; or (2) take or refrain from taking any other form of administrative action. For example, the petition process can be used by a drug company to request a change in the approval standards for generic competitors; a food trade association can request that FDA establish exemptions from certain package labeling requirements; or a consumer group can petition FDA to tighten regulation of a certain product, such as tobacco.

Citizen petitions are submitted to FDA's Dockets Management Branch, which: (1) records the date of receipt; (2) assigns a docket number to the petition; and (3) refers the petition to the appropriate FDA organizational component for response. These organizational components are generally FDA's five centers--Center for Biologics Evaluation and Research (CBER); Center for Drug Evaluation and Research (CDER); Center for Devices and Radiological Health (CDRH); Center for Food Safety and Applied Nutrition (CFSAN); and Center for Veterinary Medicine (CVM). Any interested person may submit written comments on a petition to the Dockets Management Branch, and these comments become part of the docket file.

The FDA receives about 96 citizen petitions a year (excluding abbreviated new drug application (ANDA) suitability petitions and over-the-counter (OTC) drug monograph petitions), or about 8 per month. For the 4-month period from July through October 1997, FDA closed out 40 petitions compared to 29 for the previous 4-month period from February through June 1997. The FDA denies about 70 percent of citizen petitions.

In reviewing petitions, the Commissioner of Food and Drugs may hold conferences, meetings, discussions, and public hearings; or issue a Federal Register notice requesting information and views. The majority of citizen petitions are submitted by the regulated industry to CDER and CFS AN.

OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of this review was to assess FDA's effectiveness in handling citizen petitions and identify ways that the process can be improved.

Our review covered citizen petitions submitted under 21 C.F.R. Part 10, Section 10.30, and excluded ANDA suitability petitions and petitions to amend or repeal OTC drug monographs. We excluded these two types of petitions because different requirements apply to them. For example, ANDA suitability petitions must be answered in 90 days rather than 180 days. With respect to OTC drug monograph petitions, proposals to amend monographs-and invitations for public comments are published in the Federal Register to a greater extent than with other types of citizen petitions.

We analyzed a report of all petitions received in the Dockets Management Branch from January 1, 1993, to July 21, 1997. We also analyzed two Dockets Management Branch reports dated July 15, 1997, and November 10, 1997, of all pending petitions in FDA dating back to November 1977.

We reviewed those sections of the Administrative Procedure Act dealing with petitions, FDA regulations for processing citizen petitions, and each center's policies and procedures for implementing these regulations. We also held discussions on the citizen petition process with cognizant staff of FDA's Office of Policy, Office of Chief Counsel (OCC), and each of FDA's five centers. In addition, we reviewed citizen petition regulations of four other Federal agencies: Environmental Protection Agency (EPA), Consumer Product Safety Commission, Federal Aviation Administration, and Maritime Administration.

We reviewed the files of 30 citizen petitions to examine how FDA processed the petitions; however, we did not evaluate the merits of the decisions. We believe that these petitions, which were received in FDA between 1989 and 1997, provided a good representation of the many issues that each center must deal with in the citizen petition process. We also reviewed an August 18, 1997 document prepared for FDA by a consultant entitled, "Summary of Options Considered Since 1990 for Handling FDA Citizen Petitions."

Our review was performed at FDA Headquarters, Rockville, Maryland, from July 1997, to February 1998. The review was conducted in accordance with generally accepted government auditing standards.

RESULTS OF REVIEW

The FDA does not have an effective process for handling citizen petitions in a timely manner, as evidenced by a backlog of approximately 250 petitions that have not been fully answered, some dating to the 1970's and early 1980's. The FDA regulations require tentative or final responses to citizen petitions within 180 days. The backlog of pending petitions includes issues that the petitioners believe are matters of public safety, and some have requested FDA to ban or withdraw approval of certain products. When FDA does not answer petitions in a timely manner, the public may lose confidence in the regulatory process. Because the citizen petition process is not a high priority among FDA's various responsibilities, the agency has provided limited resources to the process, and there is little central oversight of the process across FDA program areas. Recognizing its problems with the petition process, FDA developed options during the early 1990's to improve the process; and since the start of our review, closed out slightly more petitions than it has received. We believe, however, that more can be done to reduce the backlog.

FDA IS REQUIRED BY REGULATION TO RESPOND TO CITIZEN PETITIONS

The FDA regulations in 21 C.F.R. Part 10, Section 10.30, require the Commissioner of Food and Drugs, within 180 days of receipt of the petition, to either: (1) approve the petition; (2) deny the petition; or (3) provide a tentative response indicating why FDA has been unable to reach a decision on the petition. The Commissioner may grant or deny the petition in whole or in part, and the petitioner is to be notified in writing of the decision.

CITIZEN PETITIONS ARE NOT ANSWERED IN A TIMELY MANNER

The FDA is not answering citizen petitions in a timely manner. As of November 1997, the agency had a backlog of 247 citizen petitions (i.e., not answered within 180 days) dating back to 1977. As shown below, 140, or 56.7 percent, of the unanswered petitions were received prior to 1994. See Appendix A for the number of pending petitions for each year.

<u>Year Petition Received in FDA</u>	<u>Number of Pending Petitions</u>	<u>Percent of Pending Petitions</u>
1977-1989	39	15.8
1990-1994	101	40.9
1995-1997	<u>107</u>	43.3
Total	<u>247</u>	100.0

To fully assess FDA's performance in processing citizen petitions, it would be beneficial to compare the number of petitions received to the number closed in a given year or period. However, such a comparison was not possible because FDA did not keep detailed records

(e.g., appropriate dates) of petitions closed until 1997. Data provided by FDA showed that, for the 4-month period from March through June 1997, the agency closed out 29 petitions, or 7.25 per month; and for the 4-month period from July through October 1997, it closed out 40 petitions, or 10 per month. Given that FDA receives about 96 citizen petitions a year, or about 8 per month, it appears that the agency is demonstrating progress by closing out more petitions than it receives.

While the most recent data indicate that FDA is able to handle its incoming petition workload, the chart above illustrates that the agency has a serious backlog of petitions requiring a full response. The backlog includes not only older petitions, but also a significant number in the most recent 2½-year period. Between 1995 and the first half of 1997, assuming that the agency received 250 petitions (at a rate of 100 per year), there remained about 43 percent in the pending category.

HEALTH AND SAFETY ISSUES NOT BEING ADDRESSED

By not answering petitions in a timely manner, FDA is not always addressing issues that petitioners believe are matters of health and safety. During our detailed review of 30 petitions, we identified a number that we believe could have--or should have--been handled in a more timely manner. Many petitions, including the following, appeared to have public health and safety implications:

- In September 1994, a petitioner requested that FDA halt all marketing and sales of the sleeping medication, triazolam (brand name Halcion). In its August 19, 1997 response, which denied the petition, FDA relied on data contained in an agency Halcion Task Force Report, issued in May 1996. It is not clear why FDA took almost 15 months after the task force report was issued to respond to this petition.
- In October 1991, a petitioner requested FDA to regulate the interstate mail-order prescription drug dispensing industry. The FDA did not answer (deny) this petition until August 19, 1997, even though in its response to the petitioner, FDA stated, "As you are aware, on November 29, 1990, the FDA denied an earlier petition [submitted in 1988] from you that raised many of the same issues concerning mail-order pharmacies that are the subject of this petition." Given that FDA had already addressed the petitioner's issues through an earlier petition, it does not seem reasonable for the agency to have taken almost 6 years to respond to this petition.
- A petition submitted in 1990, still unanswered, requested FDA to "ban the use of phenobarbital and label it clearly as prohibited for children under the age of three, except in the clear case of epilepsy." Phenobarbital is a drug used as an anticonvulsant, sedative, or hypnotic. The petition stated that a study found that the use of the drug

phenobarbital to control febrile² seizures in children under the age of three was not only ineffective, but also reduced the intelligence quotient (IQ) of the children by 8.4 points and that 6 months later the mean IQ of children exposed to phenobarbital was still 5.2 points lower than that of children in a control group. The petition also requested that FDA warn doctors in every effective way, including the label, that phenobarbital will reduce the intelligence of children if administered on a continuous basis.

- A petition submitted in 1990, also not answered, requested FDA to require a warning label on peanut butter since it could pose a safety problem for children due to possible choking. The petition cited a case in which a 16-month old child choked while eating peanut butter spread on bread and suffered severe brain damage.

We believe that petitions addressing matters that are public safety issues should receive high priority for handling within FDA. When such petitions go unanswered, the public may lose confidence in the regulatory process.

INEFFECTIVE CITIZEN PETITION PROCESS CAUSED BY SEVERAL FACTORS

Several factors contribute to FDA's ineffective citizen petition process. The FDA maintains that it does not have sufficient resources to handle citizen petitions in a timely manner. Other factors we identified include: (1) the absence of uniform policies and procedures; (2) an inadequate process for screening and prioritizing petitions; (3) the tentative response option that enables FDA to meet its 180-day requirement while allowing petitions to go unanswered for years; and (4) lack of central management and oversight of the process at a high level within FDA, preferably within OC. The agency, recognizing its problems with the petition process, developed options during the early 1990's to improve the process but most are still under consideration.

Limited Resources

Cognizant FDA officials maintain that the agency does not have sufficient resources to answer citizen petitions in a timely manner. These officials advised us that since petitions may be handled by scientific staff in addition to their other important work, such as product application reviews, it becomes a matter of multiple agency responsibilities competing for limited resources. However, the agency does not keep statistics on the amount of time it actually spends, or needs to spend, to perform its various activities. For example, of FDA's five centers, none could accurately estimate the time allocated to handling petitions. Without such information, it will be difficult for FDA to know what portion of its resources should be assigned to this activity.

² Pertaining to or characterized by fever.

In Fiscal Year (FY) 1998, FDA staff began reporting the time spent on their daily activities. One center, CDER, in implementing this time reporting system, stated, "In an era of limited resources and funding, Congress, industry and the American public are asking us to improve and streamline our processes and to assume a greater degree of accountability in accomplishing our mandate." The CDER's time reporting system covers almost 200 categories, including citizen petitions. We believe that all FDA components should include the time spent on citizen petitions as a reportable item.

Policies and Procedures

The FDA centers either do not have written policies and procedures for processing citizen petitions or the policies and procedures differ from one center to another. For example, CVM and CFSAN have had written procedures in place for some time. The CBER's procedures are incorporated into a document entitled, "Preparation of Federal Register Documents." The CDRH does not have written policies and procedures for processing citizen petitions, and CDER is in the process of finalizing such procedures for processing citizen petitions. None of the centers' policies and procedures provide specific criteria for determining which citizen petitions should receive priority handling. The absence of uniform optimal policies and procedures for use by all components within FDA can contribute to the untimely processing of citizen petitions. Effective policies and procedures should ensure that, at a minimum, petitions concerning public health and safety, as determined by the agency, are answered first and, to the extent possible, all petitions are answered within prescribed time frames. There should be no circumstances allowing petitions to languish within the agency for years.

Screening and Prioritizing System

As noted above, FDA's centers do not have an effective system to screen and prioritize citizen petitions to ensure that the agency responds first to petitions concerning public health and safety issues. We were advised by an FDA official that the development of such a system has been considered by the agency since the early 1990's as a possible option for improving the citizen petition process. We noted instances where petitions concerned about public health and safety issues have not been answered whereas other petitions dealing with economic or other matters were processed in a more timely manner.

Tentative Responses

The FDA's use of its tentative response option also appears to contribute to the untimely processing of citizen petitions. The regulations state that the Commissioner, within 180 days of receipt of the petition, will either approve or deny the petition or provide a tentative response. The tentative response option sometimes results in FDA satisfying the 180-day requirement without actually ruling on the petitioner's request. We determined that 134 of the 247 (54.3 percent) citizen petitions in the backlog received tentative responses, but still remain unanswered.

Our review of the regulations of four other Federal agencies with citizen petition processes revealed that none provide for a tentative response. One agency's regulations state that if the agency does not grant or deny the petition within 90 days, the petitioner could commence a civil action in a district court to compel the agency to initiate a rulemaking proceeding as requested in the petition. Another agency's regulations do not provide for a specific time frame for response, but state that the agency shall either grant or deny the petition within a reasonable time after it is filed, taking into account the resources available for processing the petition.

Several FDA officials advised us that because of the complexity of some citizen petitions and the amount of time needed to research the issues and develop a position, they cannot be answered within 180 days and a tentative response is necessary. We believe that in those cases where a tentative response must be used, the response should include an estimate of when a final response will be issued and, to the extent possible, a preliminary indication of whether FDA will approve or deny the petition.

Management and Oversight

The FDA does not centrally monitor the citizen petition process to ensure that it is efficient and effective. Monitoring of the petition process is generally confined to the responsible FDA centers, with occasional status reports prepared by the Dockets Management Branch. We believe that elevating the management and oversight of the citizen petition process to OC will help ensure that the centers will answer petitions in a more timely manner.

FDA Has Studied the Citizen Petition Process, But Has Not Implemented Most Recommendations

An FDA task force, convened in the early 1990's, developed several options for reducing the citizen petition backlog, but the agency has not implemented most of them. One of the options suggested by the task force would involve contacting petitioners whose petitions had been pending for a long time and offering them the opportunity to withdraw the petition. According to an FDA official, this option was implemented with limited success.

Other options suggested by the FDA task force, but never implemented, included:

(1) revising the regulations to **define** a citizen petition more narrowly; (2) responding only to petitions for new rulemaking or changes to existing regulations; (3) screening and prioritizing petitions and responding first to high priority petitions; and (4) assigning routing and tracking of citizen petitions to FDA's Executive Secretariat. Because these options appear to have some merit, we believe they should be thoroughly discussed within the agency and implemented where practical.

Another option currently being considered within FDA is to deny certain petitions on resource grounds. The FDA's OCC has determined that, in appropriate cases, FDA can deny a citizen

petition because the agency lacks the resources to undertake the requested action or to address in detail the issues that the petition presents. Petition denials are reviewable by the courts, which would determine whether FDA has considered the relevant factors of the petition and has adequately explained the facts and policy that led the agency to reach its conclusion. At the request of the Office of Policy, FDA's Chief Counsel, on May 5, 1997, prepared this option for FDA's Deputy Commissioner for Policy, and it is still under consideration within the agency. Should FDA implement this option, we believe the agency should have quantitative data to specifically show why it lacks resources to respond to the petitions. This could prove problematic because, as noted earlier in this report, none of the five FDA centers could accurately estimate time allocated to the petition process.

CONCLUSIONS

The FDA monitors the manufacture, import, transport, storage, and sale of \$570 billion worth of products each year. The citizen petition process is one of FDA's key mechanisms for giving the public the opportunity to provide input regarding the agency's business. However, FDA is not responding to citizen petition requests in a timely manner. When petitioners have to wait years for an answer to their petitions, particularly those that they believe deal with public safety issues, confidence in the process can suffer. The FDA is aware of this problem and is considering various options to improve the citizen petition process. We believe that these options should be promptly implemented where practical. This report includes additional recommendations for consideration by FDA.

RECOMMENDATIONS

We recommend that the Commissioner of Food and Drugs:

1. Correspond with petitioners whose requests are of long standing to determine if they still want FDA to take action on their petitions;
2. Publish a notice in the Federal Register for petitioners who do not respond to FDA's correspondence notifying them that their petitions will be removed from agency records and the reasons why unless advised otherwise;
3. Establish time-phased target dates for eliminating the remaining citizen petition backlog by handling first the oldest petitions with the most serious public health implications;
4. Include in all tentative responses to petitioners an estimate of when a final response will be issued and, to the extent possible, a preliminary indication of whether FDA will approve or deny the petition;

5. Develop agency-wide optimal policies and procedures to be used by all organizational components for responding to citizen petitions;
6. Include time spent working on citizen petitions as a category of the agency's time reporting system; and
7. Establish management and oversight responsibility for the citizen petition process in the Office of the Commissioner (OC) and implement a reporting system in which all citizen petitions still pending after 1 year are reported to o c .

FDA COMMENTS AND OIG RESPONSE

On June 18, 1998, we received FDA's written comments to the recommendations contained in a draft of this report, dated March 25, 1998. The FDA provided general and technical comments, which we incorporated where appropriate or discuss below. The agency also commented on each recommendation. The FDA comments are included in their entirety in this report as Appendix B.

OIG Response to FDA General and Technical Comments

Because FDA provided a number of general and technical comments that we did not incorporate, we provide below our rationale for not including them:

1. The FDA commented that our report should note in the **Summary of Findings and Results of Review** that: "The FDA assigns matters of highest public health concern the highest priority for work." We did not incorporate this sentence into the text where FDA suggested because we did not identify the existence of policies and procedures for prioritizing the petitions. Further, we discussed in the report under the section entitled, **Screening and Prioritizing System**, our finding that certain petitions dealing with public health and safety have not been answered whereas other citizen petitions dealing with economic or other matters were processed in a more timely manner.
2. The FDA commented that our report should note that the agency is now responding each month to more petitions than before. We believe we address this concern in our discussion in the section entitled, **Summary of Findings**, where we state that since the start of our review, FDA closed out slightly more petitions than it has received.
3. The FDA commented that our report should note that the agency now maintains various logs and listings regarding status of citizen petitions. We believe this concern is addressed in the section entitled, **CITIZEN PETITIONS ARE NOT ANSWERED IN**

A TIMELY MANNER, where we acknowledge that such information became available in 1997.

4. The FDA commented that our report should mention that not all centers have a time reporting system. We acknowledge in the section entitled, **Limited Resources**, that not all centers have a time reporting system.
5. The FDA commented that our report should note that CDER's draft procedures for the handling of citizen petitions included criteria for determining which petitions should receive priority handling. While we acknowledge that CDER is developing a system for prioritizing its regulatory activities, including citizen petitions, our work showed that the Center does not yet have a specific policy for prioritizing individual petitions in terms of their importance for being answered.
6. The FDA commented that our examples of other agencies' handling of citizen petitions may not be appropriate, implying that FDA had a larger "jurisdictional reach." We understand that FDA has complex and far-reaching responsibilities in regulating many different products, and that its citizen petition process is rather broad. However, other Federal agencies, such as EPA, also have a wide range of responsibilities regarding public health and consumer protection.
7. The FDA commented that it may be difficult to estimate when a final response to a citizen petition will be issued because of several variables, such as changes in policies and priorities, and new information becoming available. Below, in our discussion of this recommendation, we urge FDA to reconsider this option because it stems from the agency's own citizen regulation.

OIG Response to FDA's Comments on the Recommendations

The FDA generally concurred with our recommendations to: correspond with petitioners whose requests are of long standing to determine if they still want FDA to take action on their petitions; publish a notice in the Federal Register for petitioners who do not respond to FDA's correspondence notifying them that their petitions will be removed from the agency's records; establish target dates for eliminating the petition backlog by handling first the oldest petitions with the most serious public health implications; develop agency-wide optimal policies and procedures for responding to citizen petitions; and include time spent working on petitions as a category of the agency's time reporting system.

The FDA did not agree with our recommendation to include in all tentative responses to petitioners an estimate of when a final response will be issued and, to the extent possible, a preliminary indication of whether FDA will approve or deny the petition. The agency believes that such an indication while policy is under development would be misleading and

unconstructive. The FDA further stated that it is often impossible to predict with any reliability when a response would be complete, since so many factors are involved in preparing a response.

While we understand FDA's position, we would like to point out that our recommendation essentially stemmed from FDA's own citizen petition regulation at 21 C.F.R. 10.30(e)(2)(iii), which states that the tentative response may indicate the likely ultimate agency response and may specify when a final response may be furnished. Because the regulation contains such a provision, we urge FDA to reconsider its position on this recommendation.

Concerning recommendation number 7, which calls for OC monitoring and oversight of petitions that are pending longer than 1 year, FDA was not clear why we designated petitions pending more than 1 year as the population to be reported to OC. Our intent in specifying the 1 year was to ensure that OC was aware of petitions pending beyond what the petitioner might view as an acceptable period of time. The OC could then, if necessary, provide the centers with assistance to step up the response time. We further believe that close monitoring of the age of petitions at the OC level, i.e., outside of the centers that actually answer them, will prevent future backlogs.

APPENDICES

APPENDIX A

PENDING CITIZEN PETITIONS
(OVER 180 DAYS)
NOVEMBER 1977 TO JUNE 1997

<u>DATE RECEIVED</u>	<u>NUMBER OF PENDING PETITIONS</u>
1977	1
1979	1
1980	2
1982	1
1983	3
1984	1
1985	5
1986	6
1987	6
1988	6
1989	7
1990	10
1991	19
1992	21
1993	21
1994	30
1995	28
1996	38
1997	<u>41</u>
Total	247



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

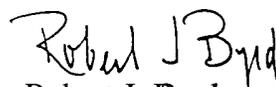
Date: JUN 18 1998

From: Deputy Commissioner for Management and Systems

Subject: Review of the Food and Drug Administration's Citizen Petition Process - Comments

To: June Gibbs Brown
Inspector General

Thank you for the opportunity to review and comment on the OIG Draft Report entitled, "Review of the Food and Drug Administration's Citizen Petition Process." The attached comments have been prepared in response to the report and recommendations.


Robert J. Byrd

Attachment

AGENCY COMMENTS ON OFFICE OF INSPECTOR GENERAL DRAFT REPORT
REVIEW OF FOOD AND DRUG ADMINISTRATION'S CITIZEN PETITION PROCESS"
(A-15-97-50002), MARCH 1998

General and Technical Comments

Page 1. Summary of Findings, and Page 2 Results of Review - After the first sentence, insert "FDA assigns matters of highest public health concern the highest priority for work. Some of the concerns raised in citizen petitions are not of the highest public health concern."

Page 1. Summary of Findings- mentions a backlog of approximately 250 petitions that have not been fully answered with some dating back to the 1970s. It should be noted that FDA is now responding each month to more petitions than before.

Insert The FDA regulations require "tentative or final" responses to citizen petitions within 180 days.

Page 3 - The report states that "FDA did not keep detailed records (e.g., appropriate dates) of petitions closed until 1997." It should be noted that the Dockets Management Branch maintains various logs and listings that now make this information available.

Page 5. First Sentence - The first sentence implies that FDA should assign the highest priority to petitions that the petitioners (rather than the Agency) believe to be "public health and safety issues." This would probably not be a helpful criterion because either most, if not all, petitioners would believe that their petitions present public health and safety issues. The petitioner could simply reformat or rephrase the petition to present such issues.

Page 5. "Limited Resources"- Please note not all Centers have a time reporting system.

Page 6. Lines 2-4- It should be noted that CDER's current draft procedures for the handling of citizen petitions include criteria for determining which petitions should receive priority handling.

Page " ening and Prioritizing Systems"- It should be noted that it is important that the Agency, not the petitioner, determine the priority that a petition should be given . The petitioner, merely by claiming to raise a public health issue, should not divert scarce resources from what, in the Agency's view, are more pressing matters.

Page 6. "Tentative Responses". Second Sentence - The draft compares FDA to four other federal agencies. The report does not state that no other federal agency has a petition mechanism that is &road as FDA's. Most other agencies tend to limit the subject matter for petitions. Additionally, given their jurisdictional reach, other agencies may not regulate as many different products as FDA, so the "universe" of petitionable subjects may be

smaller. This comparison may not be as appropriate as it seems.

Pages 6 and 7. "Tentative Responses" - It may be difficult to estimate when a final response will be issued, because of several variables such as changes in policies and priorities, and new information may becoming available. These variables may cause the time estimate to change as well.

Page 8. First Paragraph - The draft creates the impression that petitions are the only means for public input; however, the Agency also receives letters, telephone calls, comments on published documents, etc.

Recommendations:

1. Correspond with petitioners whose requests are of long standing to determine if they still want FDA to take action on their petitions.

FDA Comment

We concur with the recommendation. The Center for Drug Evaluation and Research has always attempted to contact, usually by telephone, petitioners whose petitions have been pending for several years. The Center also now sends a formal registered letter to such petitioners that has the effect of withdrawing the petition within a certain timeframe, if there is no response. Given this practice a Federal Register notice to the same effect may only be necessary when a registered letter is not sent. Moreover, a formal registered letter is a better way to provide notice to a petitioner, particularly if the petitioner is a private citizen. The Center for Food Safety and Applied Nutrition also contacts petitioners by telephone to ascertain their interest in going forward with a petition.

2. Publish a notice in the Federal Register for petitioners who do not respond to FDA's correspondence notifying them that their petitions will be removed from agency records and the reasons why unless advised otherwise.

FDA Comment

We concur with the recommendation.

3. Establish time-phased target dates for eliminating the remaining citizen petition backlog by handling first the oldest petitions with the most serious public health implications.

FDA Comment

We concur with the recommendation with the understanding that the priorities for responding to citizen petitions will be based on a consideration of all priorities that are before the

Agency.

4. Include in all tentative responses to petitioners an estimate of when a final response will be issued and to the extent possible a preliminary indication of whether FDA will approve or deny the petition:

FDA Comment

We disagree with the recommendation that FDA should give a preliminary indication of whether FDA intends to approve or deny the petition. Such an indication while policy is still under development would be misleading and unconstructive. Also because of the many people and levels involved in preparing a response, and other variables, it is often not possible to predict with any reliability the time of issuance of the response until shortly before it issues.

5. Develop agency-wide optimal policies and procedures to be used by all organizational components for responding to citizen petitions.

FDA Comment

Although we agree with the recommendation, the policies and procedures should be tailored for each center because the type of petitions, as well as organizational structures, vary considerably among the different centers.

6. Include time spent working on citizen petitions as a category of the agency's time reporting system.

FDA Comment

In general, we concur with the recommendation; however, it should be noted that one of FDA's centers does not have a time reporting system.

7. Establish management and oversight responsibility for the citizen petition process in the Office of the Commissioner (OC) and implement a reporting system in which all citizen petitions still pending after one year are reported to OC.

FDA Comment

The reason for the one-year notification is unclear. The Office of the Commissioner would continually have access to the status of any petition response, therefore, notification at the one-year mark would be unnecessary. Additionally, the Dockets Management Branch has issued monthly reports of all pending citizen petitions for over 20 years.